

FORM PTO-1390 (Modified)
(REV 10-95)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

FLA-0012

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/308407

INTERNATIONAL APPLICATION NO.
PCT/EP97/05588

INTERNATIONAL FILING DATE
10 October 1997

PRIORITY DATE CLAIMED
29 November 1996

TITLE OF INVENTION

SEALING MEDIUM FOR COMPOSITE PACKAGING MATERIALS

APPLICANT(S) FOR DO/EO/US

KOCH ET AL.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☐ Certificate of Mailing by Express Mail
19. ☐ Other items or information:

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Date of Deposit 19 May 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D. C. 20231

DEBORAH EHRET
(MAILER)

Deborah Ehret
(SIGNATURE)

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR		INTERNATIONAL APPLICATION NO. PCT/EP97/05588		ATTORNEY'S DOCKET NUMBER FLA-0012	
20. The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :					
<input checked="" type="checkbox"/> Search Report has been prepared by the EPO or JPO \$840.00					
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) \$670.00					
<input type="checkbox"/> No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$760.00					
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO \$970.00					
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$96.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$840.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). <input type="checkbox"/> 20 <input type="checkbox"/> 30				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	9 - 20 =	0	x \$18.00	\$0.00	
Independent claims	1 - 3 =	0	x \$78.00	\$0.00	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$840.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable).				<input type="checkbox"/>	\$0.00
SUBTOTAL =				\$840.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30				+	\$0.00
TOTAL NATIONAL FEE =				\$840.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).				<input type="checkbox"/>	\$0.00
TOTAL FEES ENCLOSED =				\$840.00	
				Amount to be: refunded	\$
				charged	\$
<input checked="" type="checkbox"/> A check in the amount of \$840.00 to cover the above fees is enclosed.					
<input type="checkbox"/> Please charge my Deposit Account No. in the amount of to cover the above fees. A duplicate copy of this sheet is enclosed.					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 12-1086 A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Jane Massey Licata Law Offices of Jane Massey Licata 66 E. Main Street Marlton, New Jersey 08053 (609) 810-1515			_____ SIGNATURE LICATA, Jane Massey _____ NAME 32,257 _____ REGISTRATION NUMBER 19 May 1999 _____ DATE		

09/308407

610 Rec'd PCT/PTO 19 MAY 1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: FLA-0012
Inventors: Koch et al.
Serial No.: PCT/EP97/05588
U.S. Serial No.: n/a
Filing Date: October 10, 1997
U.S. Filing Date: n/a
Examiner: n/a
Group Art Unit: n/a

Title: SEALING MEDIUM FOR COMPOSITE PACKAGING MATERIALS

"Express Mail" Label No. EL292151115US
Date of Deposit: May 19, 1999

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

By Deborah Ehret
Typed Name: Deborah Ehret

Honorable Commissioner for
Patents
Box PCT
Washington, D.C. 20231

Dear Sir:

PRELIMINARY AMENDMENT

Please amend the above-referenced application as follows:

IN THE CLAIMS:

Please cancel claims 1-8 and replace with following new claims:

--9. Packaging system made of composite packaging material for the sealed enclosure of products such as transdermal therapeutic systems being subject to changes due to exchange with their environment or to partial volatilization of active ingredient comprising a barrier layer on the product side to which barrier layer there is applied a heat sealing layer wherein the heat sealing layer is formed by an active ingredient-resistant layer having a layer thickness of maximally 15 g/m² weight per unit area, said active-ingredient resistant layer being applied from the liquid phase in a printing method and, after heat-activated sealing, displaying adhesion forces which are in the region of strength of the packaging materials.

10. The packaging system of claim 9 wherein the heat sealing layer covers only the sealing area.

11. The packaging system of claim 9 wherein a layer thickness of the heat sealing layer is between 2.5 and 3.5 g/m² weight per unit area.

12. The packaging system of claim 10 wherein a layer thickness of the heat sealing layer is between 2.5 and 3.5 g/m² weight per unit area.

13. The packaging system of claim 9 wherein the heat sealing layer comprises an ethylene/methacrylic acid dispersion which displays no measurable active ingredient uptake.

14. The packaging system of claim 9 wherein the barrier layer comprises aluminum.

15. The packaging system of claim 9 wherein heat sealing layer renders comprises a chemical composition which is sufficiently inert to nicotine.

16. The packaging system of claim 10 comprising a layer within the area which is enclosed by the sealing layer, said enclosed layer entering into interaction with the packaged product.

17. The packaging system of claim 16 wherein the enclosed layer is formed by a moisture absorbent layer.--

Preliminary Amendment
PCT/EP97/05588
Attorney Docket No: FLA-0012
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Remarks

Claims 1-8 in PCT/EP97/05588 have been canceled and replaced with claims 9-17 for entry into national Phase to conform the claims to U.S. practice. No new matter has been added.

Respectfully submitted,

Jane Massey Licata

Jane Massey Licata
Registration No. 32,257

Date: May 19, 1999

Law Offices of
JANE MASSEY LICATA
66 E. Main Street
Marlton, New Jersey 08053

(609) 810-1515

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Sealing medium for composite packaging materials

DESCRIPTION

The invention relates to a sealing medium for composite packaging materials, in particular for packaging transdermal therapeutic systems (TTS) with active ingredients which are volatile in some cases.

Sealing media for producing composite packaging materials of the type mentioned are known. They must be selected in respect of their properties so that they display, for example, no significant uptake of active ingredient from the TTS. Possible interactions with active substances or ancillary substances from the TTS must be strictly avoided or reduced as far as possible. In addition, the layer thicknesses of such media should be as small as possible because with large layer thicknesses there is observed to be in many cases an increased, unwanted interaction between product and packaging as a result of migration and penetration.

Comparatively thick layers of a sealing medium are also disadvantageous because the activation thereof in the brief melting process for bonding requires a comparatively large input of and time of exposure to heat for activating the sealing layer. To comply with these requirements, high-quality composite packaging materials have been used to date, and the sealing media employed therein have had to be applied in relatively large layer thicknesses between 20 and 60 microns with at least 20 g/m² because of the existing production processes. The said disadvantages arise from such large layer thicknesses.

The invention is based on the object of providing a sealing medium, with the use of which the abovementioned disadvantages and difficulties in the production of packs for active ingredient-containing plaster systems are avoided, which develops sufficiently high adhesive strengths when applied in an extremely thin layer, has the consistency of a printing ink which can be processed with conventional printing machines, allows insignificant uptake of active ingredient because of its chemical composition, in particular displays a barrier function towards volatile active ingredients such as nicotine, and can be used without difficulty in simple processes, for example without elaborate drying of a laminating adhesive or melting of a comparatively thick sealing film.

The object is achieved for a sealing medium of the type stated in the precharacterizing clause of Claim 1 of the invention by providing a heat sealing lacquer which is in the form of a liquid phase for applying extremely thin sealing layers in a printing process for example to partial areas of composite packaging materials.

The achievement of the invention is that, as a consequence of its small layer thickness, the sealing lacquer permits insignificant uptake of active ingredient. Moreover the possibility of applying the sealing lacquer of the invention in a printing process partially to areas of packaging materials means a further reduction in the amount used and thus in the costs of materials as well as possible interactions with active ingredient in the packaged plaster. The small amount of sealing medium used has advantages both in ecological and in economic respects not only for the production of plaster packaging but also for the disposal thereof. In addition, application in a printing process facilitates accurate partial use of the

sealing lacquer only in the sealing area and thus reduces interactions between product and packaging material. On the other hand, partial use of the sealing lacquer only in the sealing area means that it is possible to have packaging systems in which desired interactions, for example in the case of moisture absorbers, between product and packaging can take the desired form. By contrast, with the full-area sealing layers previously employed the films or sheets always formed a first layer completely surrounding the product of a packaging.

Further embodiments of the invention are provided as specified in the dependent claims. The result in these tests is an optimization in ecological and economic terms as a result of the small amount of sealing lacquer to be applied with the aid of conventional simple printing machines, and of the minimization of the raw materials, which are mostly very costly, used for these purposes, both for the production of the packaging materials and for the disposal thereof.

The invention makes it possible for sealing layers which can be applied thereby to packaging material areas to have weights per unit area between 1 and 15 g/m², preferably weights per unit area between 2.5 and 3.5 g/m².

In addition, one embodiment of the invention provides for the sealing medium to be or contain an ethylene/methacrylic acid copolymer dispersion and for it to result, by reason of its chemical composition, in no measurable uptake of active ingredient. By reason of its chemical composition, it has an advantageous barrier effect towards volatile active ingredients, in particular nicotine. It can furthermore be activated very advantageously, when present in the form of an extremely thin sealing layer, to form an

adhesive melt phase with, by comparison, extremely small input of and time of exposure to heat. On the one hand, energy is saved, and, on the other hand, the production speed of available systems for producing different packaging materials and packs can be considerably increased, and thus the productivity can be significantly improved.

Finally, the invention achieves adhesion forces for the sealing medium, after activation and formation of an adhesive layer, which are in the region of the strength of the packaging materials which can be bonded therewith.

Figures 1 and 2 show packages produced with a sealing medium of the invention for active ingredient-containing TTS.

Figure 1 shows a package with an upper and lower backing layer 1 and with an upper and lower barrier layer, for example an aluminium foil, and sealing lacquer layers 3 partially applied to the barrier layers 2.

Figure 2 shows a somewhat different embodiment of the package with an upper and lower backing layer 1, barrier layers 2, for example an aluminium foil, underneath which is a flat packaging element 4 which interacts with the product, for example a moisture absorber, and finally partially applied sealing lacquer layers 3.

The invention makes it possible, in both a particularly economical and a particularly ecological manner, both to produce and to dispose of specific packagings for TTS, in particular those with volatile active ingredients, and meets the object stated at the outset in an optimal manner.

Claims

1. Packaging system made of composite packaging material for the sealed enclosure of products such as transdermal therapeutic systems being subject to changes due to exchange with their environment or to partial volatilization of active ingredient, with a barrier layer on the product side to which barrier layer there is applied a heat sealing layer, characterized in that the heat sealing layer is formed by an active ingredient-resistant layer having a layer thickness of maximally 15 g/m² weight per unit area, said active ingredient-resistant layer being applied from the liquid phase in a printing method and, after heat-activated sealing, displaying adhesion forces which are in the region of strength of the packaging materials.
2. Packaging system according to claim 1, characterized by a heat sealing layer that covers only the sealing area.
3. Packaging system according to claim 1 or 2, characterized by a layer thickness of the heat sealing layer which is between 2.5 and 3.5 g/m² weight per unit area.
4. Packaging system according to any one of the preceding claims, characterized by a heat sealing layer containing ethylene/methacrylic acid copolymer dispersion, which heat sealing layer displays no measurable active ingredient uptake.
5. Packaging system according to any one of the preceding claims, characterized in that the barrier layer is formed by aluminium.

6. Packaging system according to any one of the preceding claims characterized by a chemical composition of the heat sealing layer that is sufficiently inert to nicotine.

7. Packaging system according to any one of claims 2 to 6, characterized by the presence of a layer within the area which is enclosed by the sealing area, said layer entering into interaction with the packaged product.

8. Packaging system according to claim 7, characterized in that the layer is formed by a moisture absorber layer.

2025 RELEASE UNDER E.O. 14176

ABSTRACT

A sealing medium for composite packaging materials, in particular for packaging transdermal therapeutic systems (TTS) with volatile active ingredients such as nicotine, is characterized in that it is a heat sealing lacquer which is in the form of a liquid phase for application of extremely thin sealing layers in the printing process for example to partial areas of composite packaging materials.

1/1

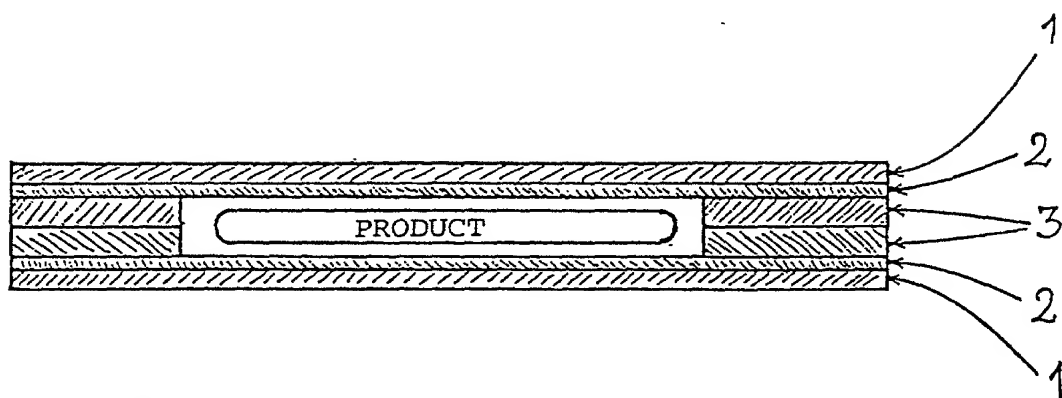


FIG. 1

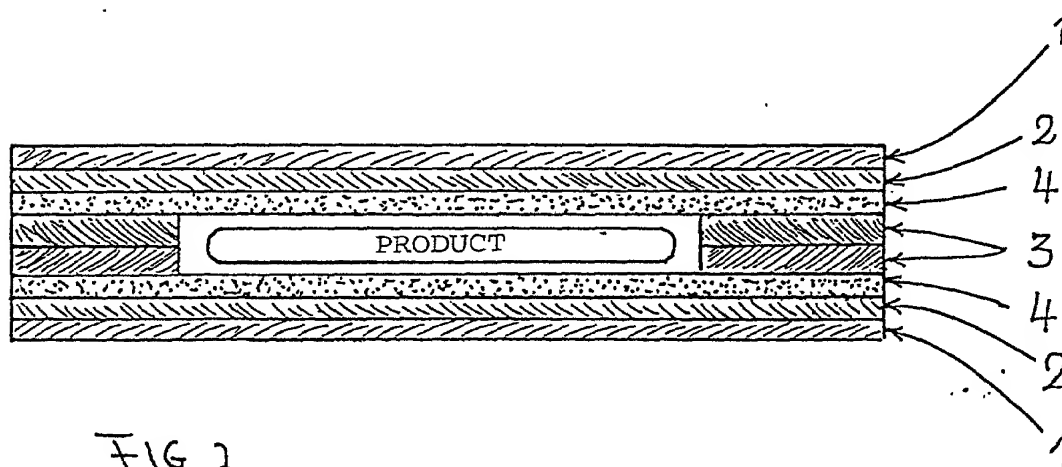


FIG. 2

"Signature" LTS 10/96
196 49 534

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and

I verily believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **Sealing Medium for Composite Packaging Materials** the specification of which:

() is attached hereto.

(XX) was filed on October 10, 1997 as Application Serial No. PCT/EP97/05588 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR \$1.56.

I hereby claim foreign priority benefits under 35 U.S.C. \$119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of any application on which priority is claimed:

Country	Number	Date Filed	Priority Claimed			
Germany	196 49 534.2	Nov. 29, 1996	Yes	X	No	
			Yes		No	
			Yes		No	

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (pending, patented)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: **Jane Massey Licata and Kathleen A. Tyrrell**, Registration Nos. **32,257** and **38,350**, respectively, of the firm of **Law Offices of Jane Massey Licata**, 66 E. Main Street, Marlton, New Jersey 08053, and

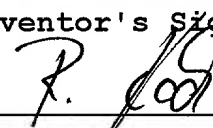

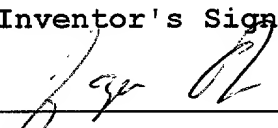
Address all telephone calls and correspondence to:

Jane Massey Licata, Esq.
Law Offices of Jane Massey Licata
66 E. Main Street
Marlton, New Jersey 08053

Telephone No.: (609) 810-1515

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1	Full Name: <u>Reinhard Koch</u>	Inventor's Signature: 	Date: <u>28.5.99</u>
	Residence: Frankenstrasse 71 b D-53489 <u>Sinzig, Germany</u> <u>DEX</u>	Citizenship: German <u>Jens Jungel</u> <u>28.05.99</u>	
	Post Office Address: Same as above.		
2	Full Name: <u>Frank Müller</u>	Inventor's Signature: 	Date: <u>28.5.99</u>
	Residence: Sattelbergstrasse 23 A-6833 <u>Klaus/Vorarlberg</u> , Austria <u>ATX</u>	Citizenship: German <u>Manfred Müller</u>	
	Post Office Address: Same as above.		
3	Full Name: <u>Jorgen Friies</u>	Inventor's Signature: 	Date: <u>28.5.99</u>
	Residence: Siland Vaenget 27 B DK-5269 <u>Odense S</u> , Denmark <u>DKX</u>	Citizenship: Denmark <u>Henrik Friis</u>	
	Post Office Address: Same as above.		
4	Full Name:	Inventor's Signature:	Date
	Residence:	Citizenship:	
	Post Office Address: Same as above.		